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510(k) Premarket Notification
Spacelabs Healthcare
Xprezzon Bedside Monitor
510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Date Prepared:	29 September 2011
Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Healthcare Xprezzon Bedside Monitor
Submitter Contact:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029 Mr. David J. Geraghty Spacelabs Healthcare Phone: +1 (425) 657-7200, ext 5889 Fax: +1 (425) 657-7210 Email: david.geraghty@spacelabs.com
Establishment Registration Number:	3026631
Proprietary Name:	Spacelabs Xprezzon Bedside Monitor, Model 91393
Common Name:	Multiparameter Patient Monitor
Classification:	Monitor, Physiological, Patient (with Arrhythmia Detections)
Product Code:	Product Code 74 MHX; 21CFR 870.1425. Class II

Performance Standard: The FDA has promulgated the *Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm* for this product classification.

NOTE: Arrhythmia functionality is implemented in the Spacelabs Medical Multiparameter Module, model 91496, not part of this submission. The model 91496 was cleared under K03142.

Predicate Device:

Device Name: Spacelabs Medical Patient Monitors
510(k) Number: K102422
Manufacturer: Spacelabs Medical, Inc.

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Device Description: The Spacelabs Healthcare Xprezzon Bedside Monitor, Model 91393, is a component of the Spacelabs Healthcare Patient Monitoring System. The Xprezzon Bedside Monitor accepts inputs from the family of Spacelabs Parameter Modules. The monitor accept and displays parameter information, waveform and numeric data, and alarm conditions including arrhythmia information received from the same family of modules. (See table).

Parameters	Model Number	Description / Comments	510(k)
Anesthesia Gas • C02 • 02 • N20 • Desflurane; • Enflurane; • Halothane; • Isoflurane; • Sevorflurane.	91518	Multigas Analyzer Module	K053599
• Carbon dioxide • Oxygen	91517	Capnography Module	K031124
• EGG • SpO2 • NIBP (optional)	90475	Telemetry Receiver Module (Requires Transmitter Module)	K050605
• EGG, • Respiration, • Invasive Blood Pressure • Non-Invasive Blood Pressure • SpO2, • Temperature, • Cardiac Output	91496	Ultraview SL™ Command Module	K103142
ECG	90492	12-Lead EGG Module	K942058
EEG, Dual Channel	90480	EEG Module	K932842
EEG	90481	EEG Module	K932842
EEG	91482	BISx Module	K060900
Mixed venous oxygen saturation	91424	SVC/ScVO 2 Module	K893867
Thermal printer	90469	2/4 channel printer Module	K842616
Thermal printer	90449	2channel printer Module	K842616

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Parameters	Model Number	Description / Comments	510(k)
Interface to External Device	90442-A	Flexport Interface Module; UNIVERSAL FLEXPORT	K903702
	90421	Flexport Interface Module, Compatible with: • NOVA515 • NELLCOR • OHMEOA	
	90433	Flexport Interface Module, Compatible with: • NORMOCAP CD-02 • NELLCOR,N-2500 • DATEX CAPNO 11 • DATEX PB254 • 5200 • N1260 • DATEX PB254	
	90434	Flexport Interface Module, Compatible with: • NOVAMETRIX 1000 • NELLCOR N1000 • CRITICARE POET	
	90435	Flexport Interface Module, Compatible with: • DINAMAP,8100,NIBP • DINAMAP NIBP	

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Parameters	Model Number	Description / Comments	510(k)
Interface to External Device (Continued)	90436	Flexport Interface Module, Compatible with: • PB7200 W/ANALOG INTRFC • PB7200 W/ANALOG INTRFC • VELA, VIASYS VENT • DRAGER EVITA 4 VENT • PB840,VENTILATOR INTERFACE • ET/AFLEXPORT, ENGSTROM • ERICANGSTROM ELVIRA • ENGSTROM ERICA/ELVIRA • BEAR 1000 • DRAGER NARKOMED 2B,2C • DRAGER EVITA 2 & EVITA 2 DURA • DRAGER VENT, INTRFC • OHMEDA 7800/10, INTRFC • HAMILTON VENT INTRFC • INFANISIAR INTRFC • ADULTSTAR • SIEMENS S300 • SIEMENS S990 • INFANT STAR INTFCRT • PB7200A/RESPIRONICS • ESPRIT • SIEMENS S990 • PB7200A	K903702
	90437	Flexport Interface Module, Compatible with; • o BRAUN BCC • o BAXTER FLO-GARD • o ABBOTT PLUM • o IVAC INFUPIMP • o IMED INFU PMP • o ABBOTT INFU PIMP	
	90438	Flexport Interface Module, Compatible with: • NOVAMETRIX 840/860 • TRANSCUTANEOUS ANAL	

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Parameters	Model Number	Description / Comments	510(k)
	90439	Flexport Interface Module, Compatible with: • PULSION P1000 • PULSION • PICCO INTERFACE	
	90443	Flexport Interface Module, Compatible with: • DRAGER CICERO EM • DRAEGER CATO • OHMEDA RASCALI1 • ENGSTROMEAS • DRAGER CICERO-B • DATEX ULTIMA W/ANALOG • OHMEDA,RGM • NARKOMED I • BICORE	
	90444A	Flexport Interface Module, Compatible with: • INCUBATOR INTFC • OHMEDA	
Interface to External Device (Continued)	90451	Flexport Interface Module, Compatible with: • Spacelabs FETAL MONITORS	**K903702**
	90519	Flexport. Interface Module, Compatible with: • 90519B,BASE UNIT	
	91436	Flexport Interface Module, Compatible with: • RADIOMETER , • GE CARESTATION, E • ENGSTROM,91436E • GE AVANCE • GE AVANCE,914360 • VIASYS ,91436C • SERVO 1,91436B • PULMONETICS	
	91438	Flexport Interface Module, Compatible with: • RADIOMETER GE • ENGSTROM CS	

The Xprezzon Bedside monitor, model 91393, is configured at installation to operate independent of or connected to the Spacelabs Patient monitoring Network. As an independent bedside monitor the device operates from AC and. presents waveform, numeric data, and alarm conditions, including arrhythmia information, received from parameter modules. When physically networked these monitors are able to share their information with a central station or with other monitors on the network according to conditions

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establish by the user/system administrator. They are also able to connect, via the healthcare institution's network, through Dynamic Network Access (DNA) to other applications available on the network.

Comparison to Predicate Device

The 91393 is substantially equivalent to their the Spacelabs Medical Ultraview SL Patient Monitors, model 91387. All devices offer the same parameter monitoring capabilities, dependant on the parameter modules employed. The model 91393 is only available as a bedside monitor and unlike the model 91387 may not be used as a central station.

The following changes were incorporated in the model 91393:

Change made to plastic material (remained PVC) giving the patient monitor a "new look". CPU boards and internal DC power supplies were also updated during this project, no functional change were made.

The maximum parameter capacities of the 91393 are the same as its predicate.

The number of internal module slots and the maximum number of remote module housings available for use with parameter modules have not changed for the 91393 from their predicate.

Display resolution has also been expanded on the 91387 and 91370 portable as technology became available. Where the 90364 was 768/1024, the 91387 resolution has been increased to 1024/768. All but one of the Spacelabs portable monitors remained identical to the predicate 90369 display resolution, with only the 91370 supporting a higher 1024/768 resolution.

The CPU PCI3A (670-1275-XX) maintenance release was implemented to improve production yield. Changes were also made as a result of employing digital signal integrity analysis tool, resulting improved signal integrity of the circuit board assembly.

The operating system was updated with the release of 2.03.OX software for the 91387, 91367, 91369 and 91370 monitors. This update, supplied by VxWorks, and adapted by Spacelabs Medical allowed for implementation of a higher level of security for the DNA and Wireless network for the monitors, as well as updating various drivers such as USB.

Intended use:

The Spacelabs Healthcare Xprezzon Bedside Monitor passively displays data generated by Spacelabs parameter modules, Flexport interfaces, and other Spacelabs SDLC based products as waveform and numeric displays, trends and alarms. Key monitored parameters available on the model 91393, when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, Sp02, temperature and cardiac output. Additional parameters and interfaces to other systems are also available depending on the parameter modules employed.

The Spacelabs Healthcare Xprezzon Bedside Monitor is intended to alert the user to alarm conditions that are reported by Spacelabs Healthcare parameter modules and/or other devices via Flexport interfaces. The Xprezzon Bedside Monitor is also capable of displaying alarm conditions on other monitors that are on the network through the Alarm Watch feature.

The Spacelabs Healthcare Xprezzon Bedside Monitor may also function as a generic display or computer terminal. As a generic display or terminal, the

patient monitor allows network based applications to open windows and display information the Xprezzon and other networked monitors.

The Spacelabs Healthcare Xprezzon Bedside Monitor is designed to communicate with a variety of external devices such as displays, network devices, serial devices, user input devices, audio systems, and local/remote recorders.

The Xprezzon Bedside Monitor is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.

Test Discussion:	The Spacelabs Healthcare Xprezzon Bedside Monitor, Model 91393, is substantially equivalent in design concepts, technologies and materials to the predicate cleared under K102422. The Xprezzon Bedside Monitor was validated through rigorous testing that, in part, support the compliance of the software to the Standards mentioned in the Software section of this submission. Additionally, the Xprezzon Bedside Monitor's software was developed following a robust software development process that was fully specified and validated. Test programs verified that parameter data provided by parameter modules, not part of this submission, to the Xprezzon Monitor could be accurately presented and that the interface supported the intended clinical work flows and met the user's clinical needs.
Test Conclusion:	The Spacelabs Healthcare Xprezzon Bedside Monitor, Model 91393, is substantially equivalent to its predicate device in design concepts, technologies and materials. Testing demonstrates that Spacelabs Healthcare Xprezzon Bedside Monitor, Model 91393 is as safe and effective as the predicate devices found substantially equivalent under K102422.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Spacelabs Medical, Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory and Compliance
5150 220th Ave SE
Issaquah, WA 98029-6834

Re: K112962
Trade/Device Name: Spacelabs Healthcare Xprezzon Bedside Monitor
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: October 3, 2011
Received: October 5, 2011

Dear Mr. Geraghty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112962

Indications for Use Form

510(k) Number (if known): K112962

Device Name: Spacelabs Healthcare Xprezzon Bedside Monitor

Indications for Use:

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The Xprezzon Bedside Monitors is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.

Prescription Use: XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112962